



DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Information Collection tool relating to the Orphan Drug Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the orphan drug credit.

DATES: Written comments should be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317-5751 or Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington DC 20224, or through the internet, at Kerry.Dennis@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Orphan Drug Credit.

OMB Number: 1545-1505.

Form Number: 8820.

Abstract: Filers use this form to elect to claim the orphan drug credit, which is 50% of the qualified clinical testing expenses paid or incurred with respect to low or unprofitable drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

Current Actions: There is no change in the form or paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 67.

Estimated Time Per Response: 4 hours, 42 min.

Estimated Total Annual Burden Hours: 316.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: September 2, 2021.

ChaKinna B. Clemons,
Supervisory Tax Analyst.

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